IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** *Wave 11 case Welch, et al. v. Ethicon, Inc., et al.*, 2:12-cv-08677, and all future Wave cases	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' *DAUBERT* MOTION TO EXCLUDE THE TVT GENERAL CAUSATION OPINIONS AND TESTIMONY OF BRUCE S. KAHN, M.D.

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Plaintiffs submit this brief in support of their Motion to Exclude the TVT General Causation Opinions of Bruce S. Kahn, M.D.

INTRODUCTION

Dr. Kahn is urogynecologist in California with experience in the treatment of stress urinary incontinence ("SUI"). Exhibit A—Expert Report of Dr. Kahn at p. 2. Dr. Kahn intends to provide general causation opinions about Ethicon's Gynecare TVT. As discussed below, the Court should exclude certain opinions of Dr. Kahn for the following reasons: (1) he is not qualified to testify on the safety and efficacy of the TVT because he has not implanted a TVT since 2005; (2) he is not qualified to opine or testify on the biocompatibility of TVT, Prolene, or polypropylene; (3) he is not qualified to opine or testify on degradation and fraying of the TVT, and his opinions are not reliable; (4) he is not qualified to testify or opine on the TVT's Instructions for Use, and his opinions are not reliable; and (5) his opinions regarding pain, erosion and exposure, and urinary problems lack necessary bases and are not reliable.

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.[1] The trial judge acts as a gatekeeper for scientific, technical and other specialized knowledge.[2] Further, in addition to specific legal citations and argument contained in this

[1] *See Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005)(federal law governs admissibility of expert testimony).
[2] *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999).

Memorandum, Plaintiffs incorporate by reference the standard of review for *Daubert* motions set forth by this Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 692, 701 (S.D. W. Va. 2014).

ARGUMENT

I. Dr. Kahn Is Not Qualified to Opine on the Safety and Efficacy of the TVT Because He Has Not Implanted a TVT Since 2005.

The Court should exclude Dr. Kahn as a general causation expert because Dr. Kahn is not qualified to testify on the safety and efficacy of the TVT. As a threshold matter, the Court must determine whether the proposed expert is qualified based on his knowledge, education, and experience concerning the issues on which he is to opine.[3] Dr. Kahn is a urogynecologist that has been treating SUI for more than twenty years; however, Dr. Kahn has not implanted a TVT for the treatment of SUI since 2005. *See* Exhibit B—Deposition of Dr. Bruce S. Kahn on General TVT Report[4] at 49:10-23, 67:20-68:19. Therefore, his disqualification arises from his lack of knowledge, experience, and understanding of the TVT product, specifically. This lack of basic familiarity with the product on which he is to opine is fatal. Ethicon cannot be allowed to present Dr. Kahn's testimony to a jury regarding the safety and efficacy of a medical device that he, the "expert," has not used in almost fifteen years. This is Ethicon educating its expert when it should be the other way around.

Many of Dr. Kahn's opinions in his General TVT Report are based on his experience and observations strictly in a clinical setting; unfortunately, his experience and observations over the last fifteen years do not include the TVT. This means he has not encountered TVT implantation and, more importantly, associated complications during that time. Put simply, Dr. Kahn has been

[3] Rule 702 states that one must be qualified to proffer expert testimony by "knowledge, skill, experience training, or education."

[4] Plaintiffs' counsel has not yet received the final version of Dr. Kahn's deposition. If the Court prefers, counsel can supplement this Memorandum once the final transcript is received.

hired to testify about the safety and efficacy of a product he has not used in almost fifteen years. Experts must be qualified, and their testimony must be helpful, but Dr. Kahn's contribution to Ethicon's defense, if any, will be minimal because his opinions are not his own. For Dr. Kahn's shocking lack of experience with the TVT, the Court should entirely exclude his testimony, in its entirety, relating to TVT general causation.

II. Dr. Kahn Is Not Qualified to Opine on the Biocompatibility of TVT, Prolene, or Polypropylene, and his Opinions Are Not Reliable.

Dr. Kahn is an experienced urogynecologist, but that does not make him qualified to testify or opine on the biocompatibility of TVT, Prolene, or polypropylene. In his General TVT Report, Dr. Kahn states:

> The design of the TVT device has many positive attributes that have made it the gold standard treatment for stress urinary incontinence. It is microporous, lightweight mesh that is known for its excellent biocompatibility…. The fact that the device is made from Prolene polypropylene is comforting for surgeons, as the integrity and biocompatibility of the material is well-known.

Exhibit A at p. 17. Dr. Kahn does not have any experience in researching or investigating the biocompatibility of the TVT product, Prolene, or polypropylene. During his deposition, Dr. Kahn was given multiple opportunities to explain his experience and qualifications to opine on TVT's biocompatibility as well as the basis for his opinions; however, he could only point to his clinical experience.

> Q: When did your research begin about the biocompatibility of the TVT product?
>
> A: Probably about the time I started performing the TVT procedure back around 2000.
>
> Q: And when you say that, are you referencing your clinical experience?
>
> A: **Right. Clinical experience** and – and research and – and attendance at meetings and, you know, are we having problems with this implant in patients. So –

> Q: Do you have any?
>
> A: -- it goes back to the breadth and depth of my – you know, **my clinical activity in general** going way back when. So…
>
> Q: Other than clinical experience in implanting the mesh and monitoring patients who have it implanted, do you have any training in the biocompatibility of products implanted in the body?
>
> A: Sure. It really goes back to my – **my experience, you know, as a physician, becoming a physician**. While I don't do research on, you know, the polymers, I – I do research with patients. I take care of patients, clinical taking care of patients.
>
> …
>
> Q: Have you ever performed your own research on the biocompatibility of certain materials in the body?
>
> A: I performed my research in the form that we discussed, that it's – **I'm taking care of patients every day**.

Exhibit B 128:4 – 129:24. Dr. Kahn makes clear that his opinions on biocompatibility are solely based on his experience as a clinician. Again, his personal experience with the TVT ended in 2005.

Dr. Kahn's clinical experience with the TVT is insufficient to qualify him to opine on the TVT's biocompatibility. To be admissible, an expert's opinions must be reliable. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999); *see also Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) ("Under [Rule] 702, trial judges act as gatekeepers to ensure that any and all scientific testimony . . . is not only relevant, but reliable.") (internal citations and quotations omitted.). Any opinions that he can offer are based almost entirely on what he has read while preparing to testify on behalf of Ethicon. If that were the standard, then anyone could testify as an expert on any matter. Dr. Kahn understands what biocompatibility is on a general level like any M.D., but he has no independent knowledge of the TVT's biocompatibility or that of Prolene or polypropylene. He also has not performed any research on the biocompatibility of the TVT, Prolene, or polypropylene.

The Court should exclude testimony and opinions from Dr. Kahn regarding the biocompatibility. He is unqualified, and he could not provide any basis for his opinions other than what he has read while preparing to testify. Any testimony on this subject would only serve to confuse the jury, and he certainly would not assist the jury in analyzing the evidence regarding biocompatibility.

III. Dr. Kahn is Not Qualified to Testify or Opine on Degradation or Fraying of the TVT, and His Opinions Are Not Reliable.

Dr. Kahn is also not qualified to testify or opine on the TVT degrading and fraying because he has no experience in testing, examining, or researching the TVT mesh. Further, Dr. Kahn testified that degradation and fraying were new concepts to him when Ethicon hired him:

> Q: What did you do to perform your own research?
>
> A: Starting with internet-based searches, looking for whatever topic I'm trying to look at with – you know, in the realm of TVT's, whether it be complications or – **I honestly had to learn a lot about – in reviewing some of the plaintiffs' expert reports, a lot of that information was new information**, and I wanted to go out and see if there was anything, and I wanted to go out and see if there was anything, you know, to these things about degradation and fraying.
>
> And, you know, **this was all kind of things that I hadn't really heard much about in the past**, and I hadn't had any clinical problems regarding them. So I did spend a fair amount of time seeing – searching out to see what there was that I could find, you know, anything out there that I'm kind of missing. That would be a good example of something. So mostly internet searches. And then when I would – you know, go find – look for the article and see if there was anything there.
>
> But I can't remember any specifics for you, but that's the basic mechanism. It was basically using an internet search.
>
> Q: You mentioned a few topics that you – that were somewhat new to you in reading the plaintiffs' expert reports, and you identified degradation and fraying. Is that right?
>
> A: Correct.

Exhibit A at 91:21 – 93:1. Both degradation and fraying are subjects on which the Court should not allow Dr. Kahn to testify or opine. Ethicon has attempted to create an expert out of a doctor that is unqualified. His experience as a gynecologist and urogynecologist leading up to his hire do not provide him the knowledge, education, or experience necessary to provide helpful, reliable testimony to the jury on these subjects. It would be appalling to the *Daubert* standard to allow an expert to testify in front of a jury on matters that were "all kind of things that [he] hadn't really heard much about" before being hired. *Id.*

A. Dr. Kahn is Not Qualified to Testify or Opine on Degradation of the TVT, and His Opinions Are Not Reliable.

Regarding degradation, Dr. Kahn states in his TVT General Report:

> The published studies and my own experience with polypropylene mesh mid-urethral slings including the TVT demonstrate that the material does not degrade; the slings are effective in the long-term and very well-tolerated by the body.

Exhibit A at 20. Dr. Kahn had not investigated or researched degradation of the TVT until he was hired by Ethicon; and the only research he has done since being hired is superficial. During his deposition, Dr. Kahn testified as follows:

> Q: What about degradation of the mesh product, do you have any opinion as to whether it does or does not degrade inside the body?
>
> A: I've seen some internal documents, and the experts – the plaintiffs' expert' opinions about that **and looked at that a little bit**. And I think there is some – while there was an argument made that there was some degradation happening, what it really turned out to be is that there was just a coating that looked like fraying, but when the coat – when the coating was taken off, that the polypropylene itself or the Prolene itself really had not degraded. And do I don't think there's any degradation that occurs.
>
> Q: You –
>
> A: I don't think **this stuff** disintegrates in the body.
>
> Q: And if you think it doesn't disintegrate or degrade in the body, then I assume your opinion is also that degradation doesn't cause any complications with the mesh.

> A: That is true.
>
> Q: Okay. But truly your opinion is that you don't believe there's any degradation that occurs.
>
> A: I don't think there's any clinically significant issues with degradation.
>
> Q: And instead, your opinion – your belief is that there's a – a coating that form on the mesh.
>
> A: That is the data I've reviewed.
>
> Q: How much data did you review regarding degradation.
>
> A: Quite a bit actually. The report – and I can't cite them verbatim for you, but there was a lot of – I think I was provided with a lot of what your experts – what the plaintiffs' experts were using in their arguments, and I looked at that data, and I looked at what – you know, some other contrasting data to – to counteract those arguments, and it really appears that it doesn't degrade.

Exhibit B at 169:9 – 170:24. Dr. Kahn was not able to articulate what the basis was for his opinion. He thinks he was provided what the Plaintiffs' experts relied upon, and then he looked at some contrasting data "to counteract those arguments." *Id*. Then, again, Dr. Kahn admitted he was simply relying on his clinical experience with patients. Dr. Kahn added:

> A: But let me just add, more importantly clinically, what happens to my patients, what happens to our patients that we take care of, I've been using this stuff for 20 years for treating urinary incontinence, and it just – degradation is not a problem. It's just not a clinical problem.
>
> Q: Before you began your work as an expert witness in this litigation, had you researched degradation specifically?
>
> A: To that point, again, **clinically,** are my patients having problems. **So that would be the extent of my research with regard to degradation**.
>
> …
>
> Q: Prior to your work beginning in this litigation, Doctor, had you ever wondered to yourself, does the mesh – does the TVT mesh degrade inside the body?
>
> A: **I hadn't ever worried about it** because it's Prolene suture, and my understanding that I was taught as a resident was the Prolene is permanent.

Exhibit B at 171:22 – 172:5.

First, Dr. Kahn has not been using "this stuff" for fifteen years. He clearly testified that he has not implanted a TVT since 2005, and his opinions about non-TVT products are irrelevant here. Second, Dr. Kahn admitted he is mostly relying on his clinical experience, which is not the same as investigating degradation of the TVT. As discussed previously, Dr. Kahn admitted degradation and fraying were, "a**l**l kind of things that I hadn't really heard much about" until he was provided information by Ethicon. *Id*. at 92:8-10. His testimony amounts to nothing more than: I never saw it, so it never happened. Or rather, I was never worried about looking for it, so I never saw it, so it must have never happened. Dr. Kahn's opinions lack a sufficient basis and are, therefore, unreliable. The Court should preclude Dr. Kahn from opining on degradation.

B. Dr. Kahn is Not Qualified to Testify or Opine on Fraying of the TVT, and His Opinions Are Not Reliable.

Dr. Kahn is similarly ill-equipped to testify on fraying of the mesh. Dr. Kahn testified as follows:

> Have you ever done any studies on the fraying of mesh or polypropylene, Doctor?
>
> A: I guess you could say I've done a pretty good study for 20, 25 years with my own patients, and I have not found that to be a problem.
>
> …
>
> Q: Doctor, have you ever conducted a study specifically geared at looking at fraying of mesh or polypropylene?
>
> Mr. Koopman: Object to form.
>
> A: I have not.
>
> Q: Doctor, have you ever –
>
> A: But again, I want to go back to adding that, you know, it's something that I've paid attention to in my clinical care of patients, and it just hasn't been an issue.
>
> Q: Were you looking for fraying in the mesh in 2000 when you began using the TVT product?

A: I was looking for how my patients were doing and to seeing if there were any problems.

Exhibit B at 99:12 – 100:9. Again, fraying was a new concept to Dr. Kahn when he began his preparation to testify as an expert witness. Ethicon cannot be allowed to teach its expert about the subjects on which he is to testify. Dr. Kahn's opinions on fraying lack a sufficient basis and, therefore, are unreliable. The Court should preclude Dr. Kahn from opining on the fraying of TVT.

IV. Dr. Kahn Is Not Qualified to Testify or Opine on the Warnings in the TVT's Instructions for Use, and His Opinions Are Not Reliable.

The Court should exclude Dr. Kahn's opinions on the adequacy of the warnings contained in the TVT's Instructions for Use ("IFU"). Dr. Kahn has not articulated any knowledge of the FDA regulations concerning warnings or other contents of an IFU. He also has not explained any experience with drafting warnings or other contents of an IFU. In the "Background" section of his General TVT Report, Dr. Kahn outlines his history of clinical experience, faculty appointments, and research interests. Exhibit B at 2. The only mention of the FDA in his background is his involvement as an investigator on FDA mandated "522" trials for two mesh products (neither TVT). *Id.* at 3.

Dr. Kahn gives the blanket opinion: "the IFU accompanying the TVT device was adequate and allowed surgeons to safely use the device to treat SUI." Exhibit A at 22. Being a urogynecologist who understands the pelvis does not qualify one to be an expert on the adequacy of IFU labeling, device warnings, or FDA compliance. Additionally, Dr. Kahn does not cite to a particular version of the TVT's IFU or indicate that he is familiar with the history of the TVT's IFU. The Court should exclude this catch-all opinion. *See Sanchez et al. v. Boston Scientific Corp.*, 2014 WL 4851989, at *35 (S.D.W.Va. Sept. 29, 2014) ("Given that the probative value of expert

testimony on FDA requirements is substantially outweighed by the risk of jury confusion, I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations.").

Dr. Kahn also opines: "The device's IFU, in my opinion, did not need to include mention of risks that are not supported by published medical literature, such as a risk of shrinkage, particle loss of clinical significance, fraying, roping/curling, cancer, inadequate pore size, heavyweight, or chronic foreign body reaction that is clinically significant." *Id.* He provides no support for this opinion. Additionally, some of the items in this laundry list were "new information" and "all kind of things that [he] hadn't really heard much about" Exhibit A at 91:21 – 93:1. Dr. Kahn is not qualified to opine on the adequacy of the TVT's IFU, and his opinions are nothing more than speculation based on his own experience as a clinician. As such, the Court should preclude Dr. Kahn from opining on the adequacy of the TVT's IFU and related warnings.

V. Dr. Kahn's Opinions Regarding Pain, Erosion and Exposure, and Urinary Problems Lack the Necessary Bases and Are Not Reliable.

The Court should exclude Dr. Kahn's causation opinions regarding pain, erosion, and urinary problems. In his General TVT Report, Dr. Kahn states:

- When pelvic pain, vaginal pain, or dyspareunia occur following a TVT surgery, it is not the result of… any inherent characteristic of the device.
- Mesh erosions or exposures are not attributable to… any inherent characteristic in the TVT device.
- Recurrent incontinence is not caused by… any inherent characteristic of the TVT device.

See Exhibit B at 17 – 19. These opinions are self-serving and not grounded in logic or coherent thought. As previously stated, Dr. Kahn opines in his section on the Instructions for Use that the TVT's IFU did not need to warn about "pain, pain with intercourse, or recurrent incontinence" because those risks should be common knowledge to licensed pelvic floor surgeons implanting a TVT. *Id.* at 22.

Dr. Kahn also writes in his General TVT Report, "The risk of mesh exposure or erosion is arguably unique to mesh-based surgeries…" *Id.* at 22. Dr. Kahn continues to explain that "Ethicon published the Surgeon's Resource Monograph to provide surgeons with expert opinions from a 17-surgeon panel on the use of the TVT device. The monograph provided guidance on […] potential complications including […] urethral erosion, mesh protrusion, infection of the mesh, UTI, and device failure." *Id.*at 23. These blanket opinions from Dr. Kahn are void of support or basis, and they will be confusing to the jury considering the literature and internal Ethicon documents they will see which acknowledge that pain, erosion and exposure, and recurrent incontinence are all known complications and adverse reactions of the TVT, some of which Dr. Kahn cites in his General TVT Report. Therefore, the Court should preclude Dr. Kahn from making these grandiose, unsupported, and unreliable causation opinions.

CONCLUSION

In conclusion, Plaintiffs respectfully request the Court should exclude certain opinions of Dr. Kahn because: (1) he is not qualified to testify on the safety and efficacy of the TVT because he has not implanted a TVT since 2005; (2) he is not qualified to opine or testify on the biocompatibility of TVT, Prolene, or polypropylene; (3) he is not qualified to opine or testify on degradation and fraying of the TVT, and his opinions are not reliable; (4) he is not qualified to testify or opine on the TVT's Instructions for Use, and his opinions are not reliable; and (5) his opinions regarding pain, erosion and exposure, and urinary problems lack necessary bases and are not reliable.

Dated: August 15, 2019

Respectfully submitted,

/s/ *Jim M. Perdue, Jr.*
Jim M. Perdue, Jr., Esq.
PERDUE & KIDD
777 Post Oak Blvd, Suite 450
Houston, Texas 77056
Tel: (713) 520-2500
Fax: (713)520-2525
jperduejr@perdueandkidd.com

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on August 15, 2019, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ *Jim M. Perdue, Jr.*
Jim M. Perdue, Jr., Esq.
PERDUE & KIDD
777 Post Oak Blvd, Suite 450
Houston, Texas 77056
Tel: (713) 520-2500
Fax: (713)520-2525
jperduejr@perdueandkidd.com